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(54) **SYSTEM AND METHOD FOR NAVIGATING A GUIDE WIRE**

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CPC **A61B 34/70** (2016.02); **A61B 34/25** (2016.02); **G16H 20/40** (2018.01); **G16H 30/40** (2018.01);
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See application file for complete search history.

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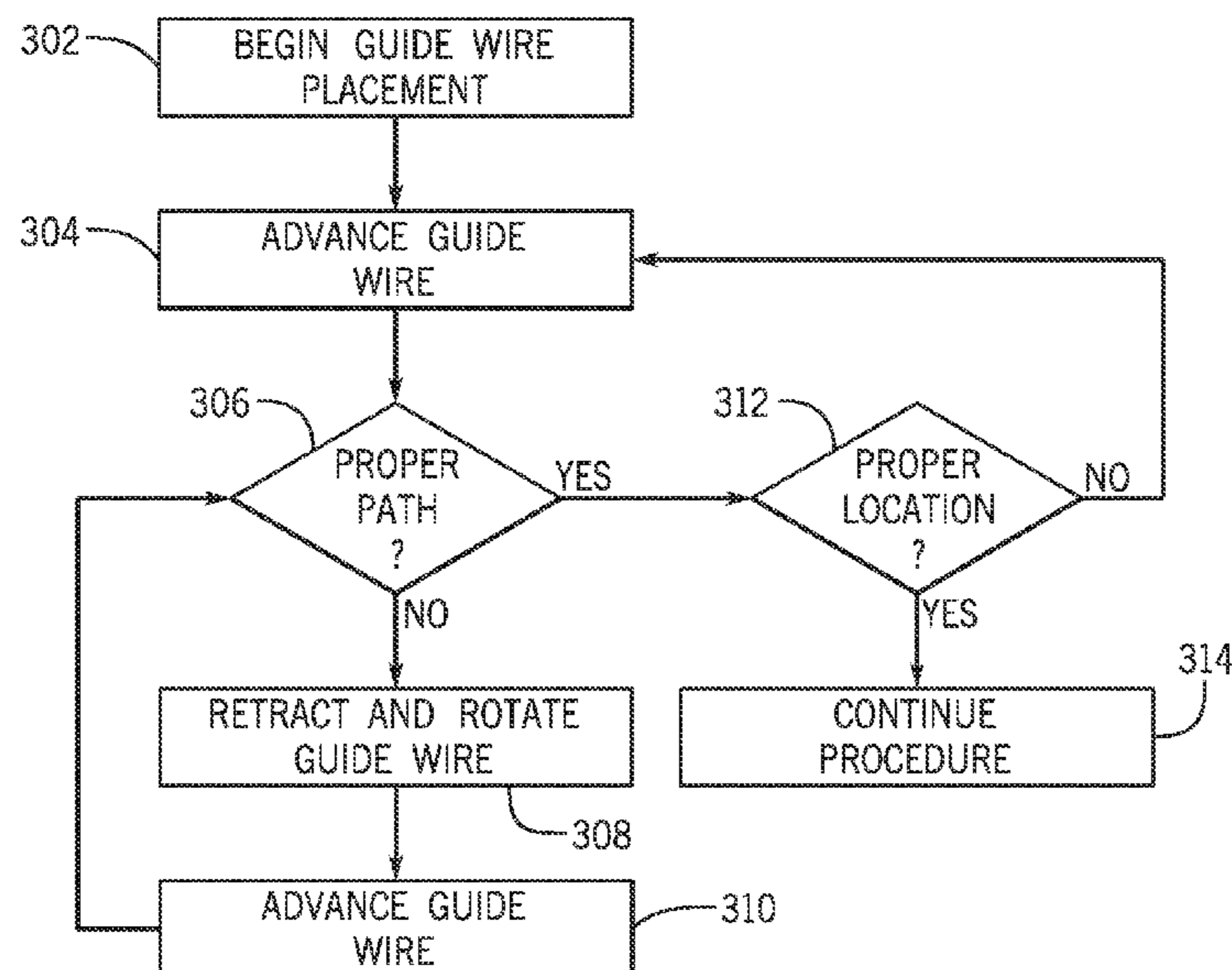
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(57) **ABSTRACT**
A method for navigating a guide wire during a catheter procedure, the method includes changing the direction of a distal portion of the guide wire to advance past a junction in a desired path by rotating a proximal end of the guide wire a predetermined amount while the guide wire is being retracted to a point before the junction and then advancing the distal end of the guide wire past the junction through the desired path.

22 Claims, 7 Drawing Sheets



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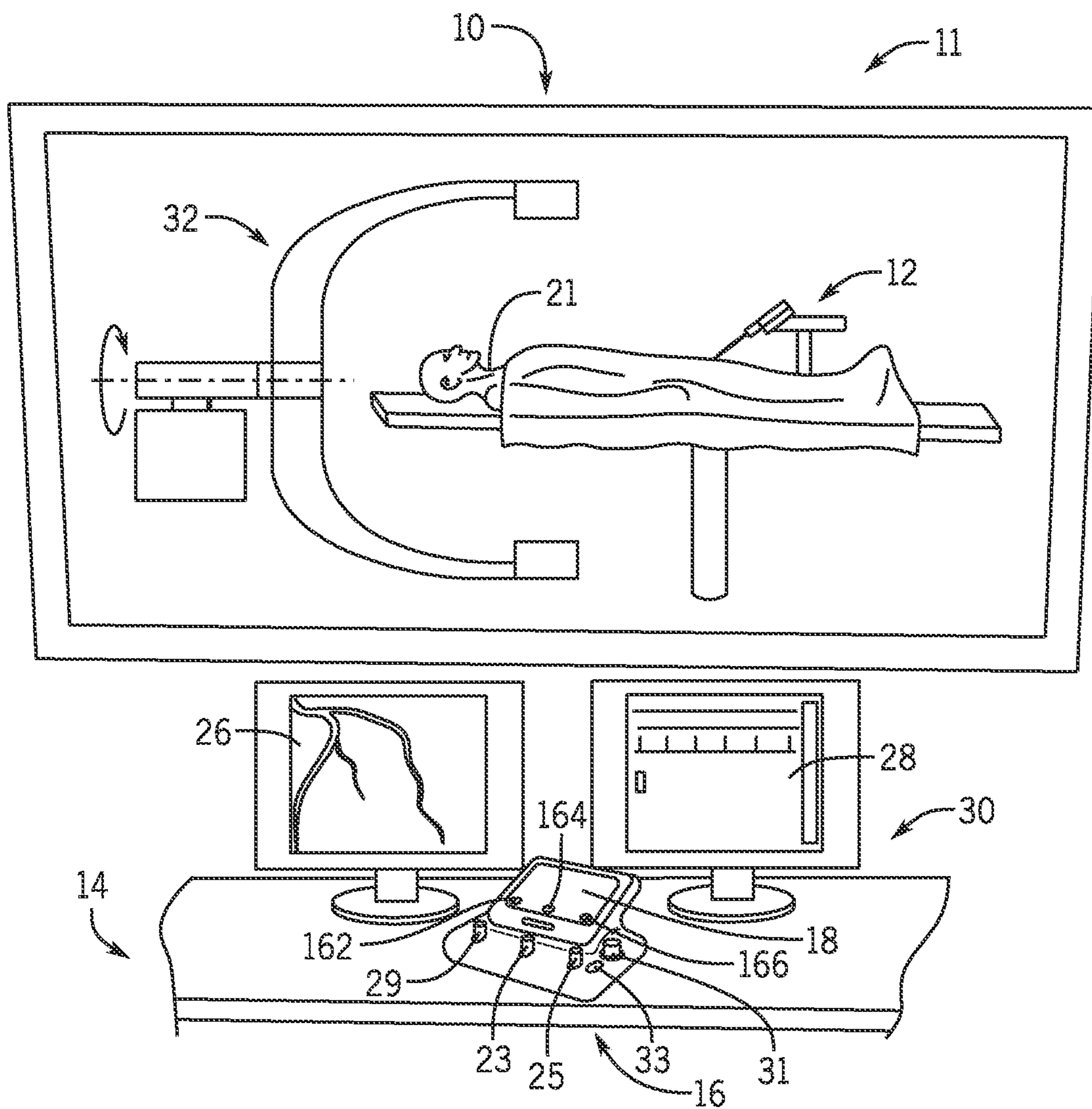


FIG. 1

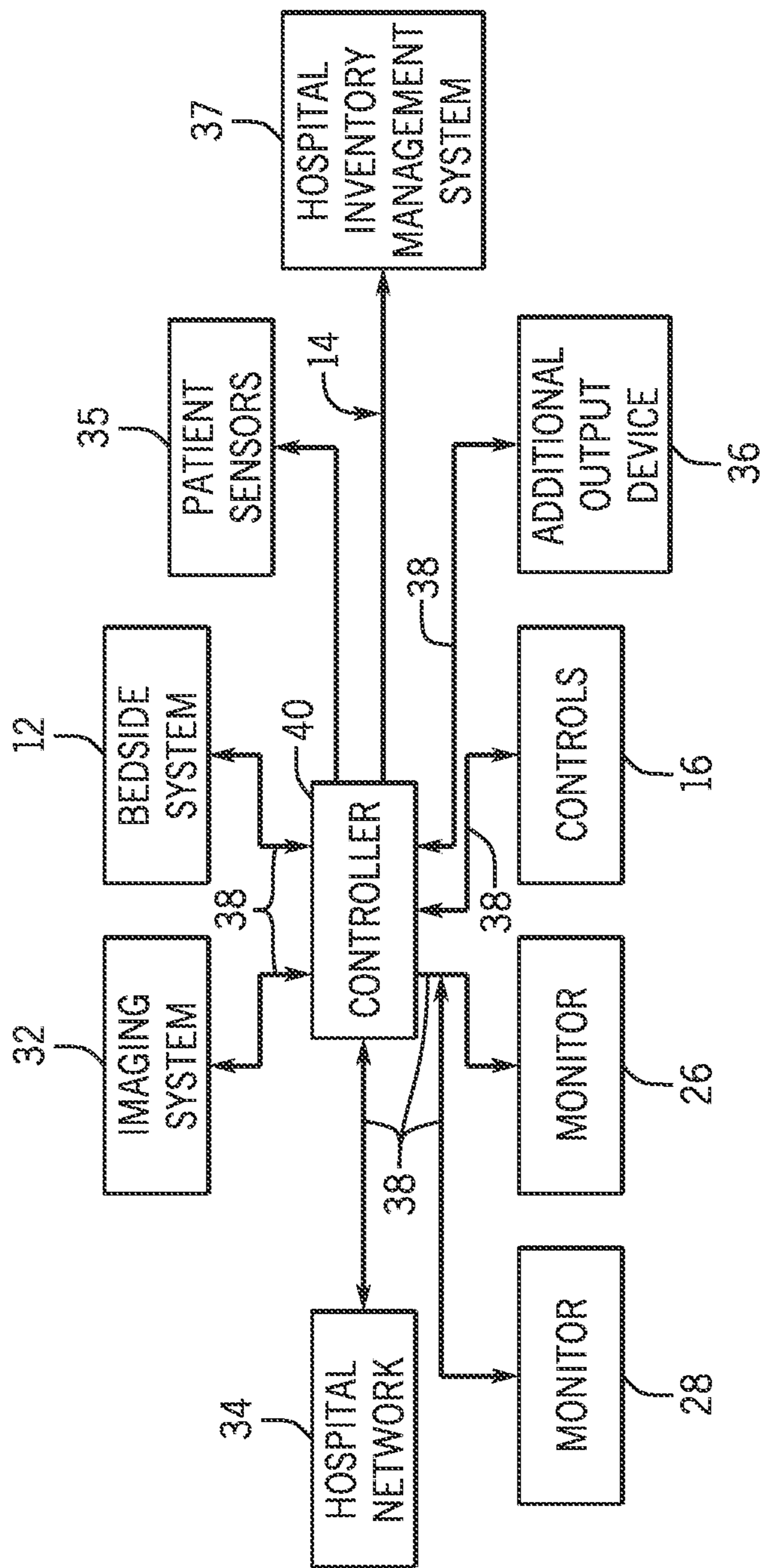


FIG. 2

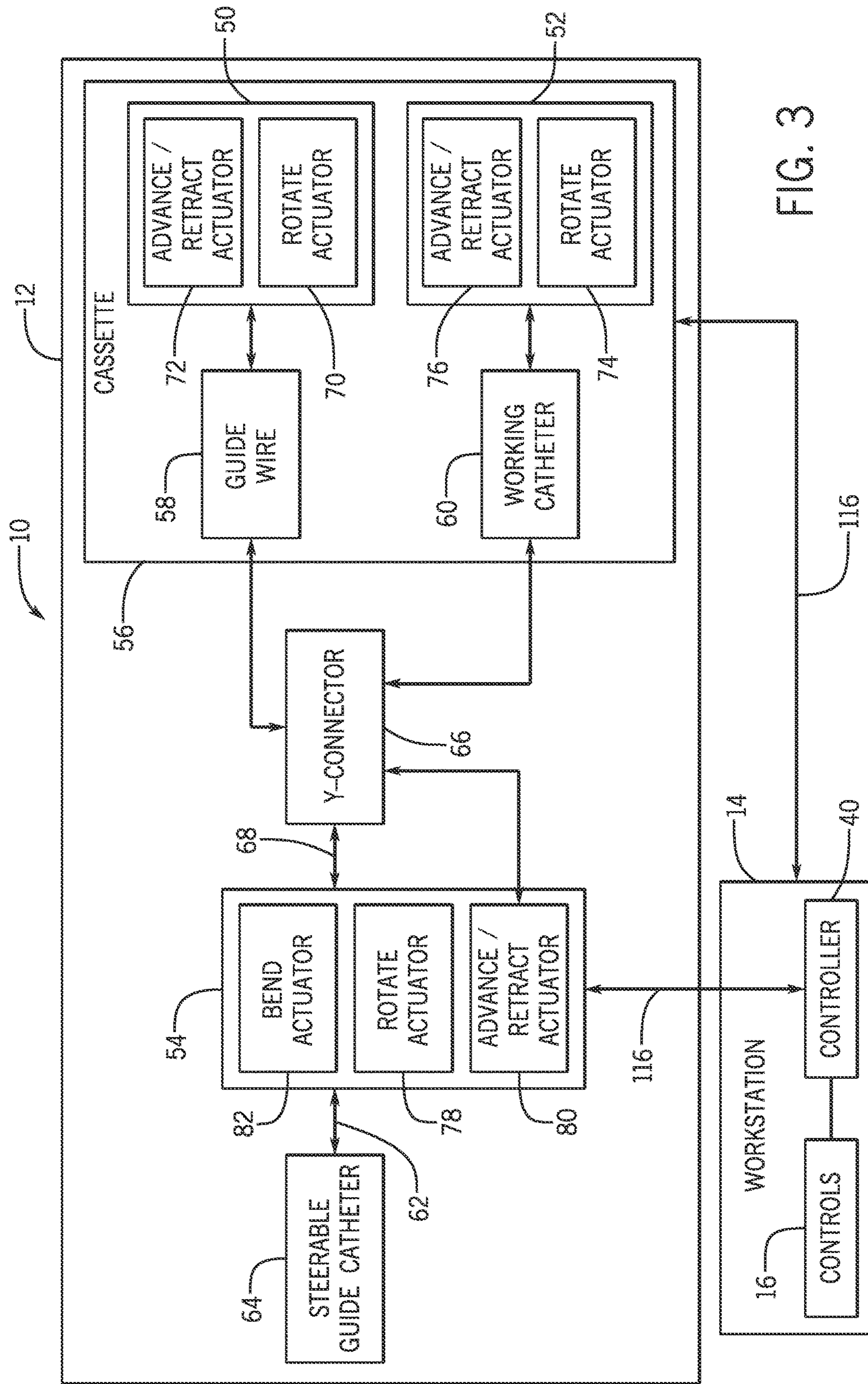


FIG. 3

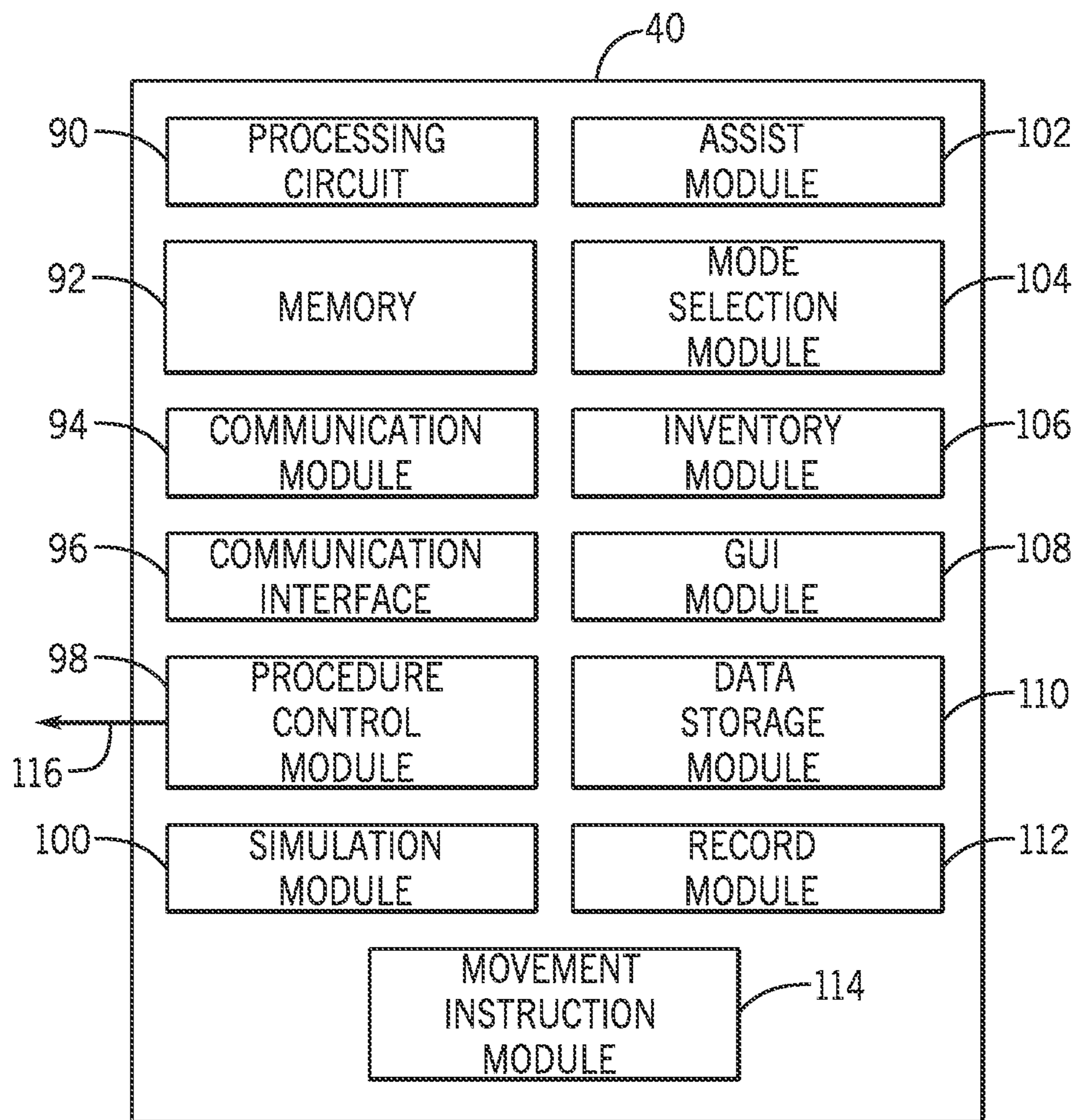


FIG. 4

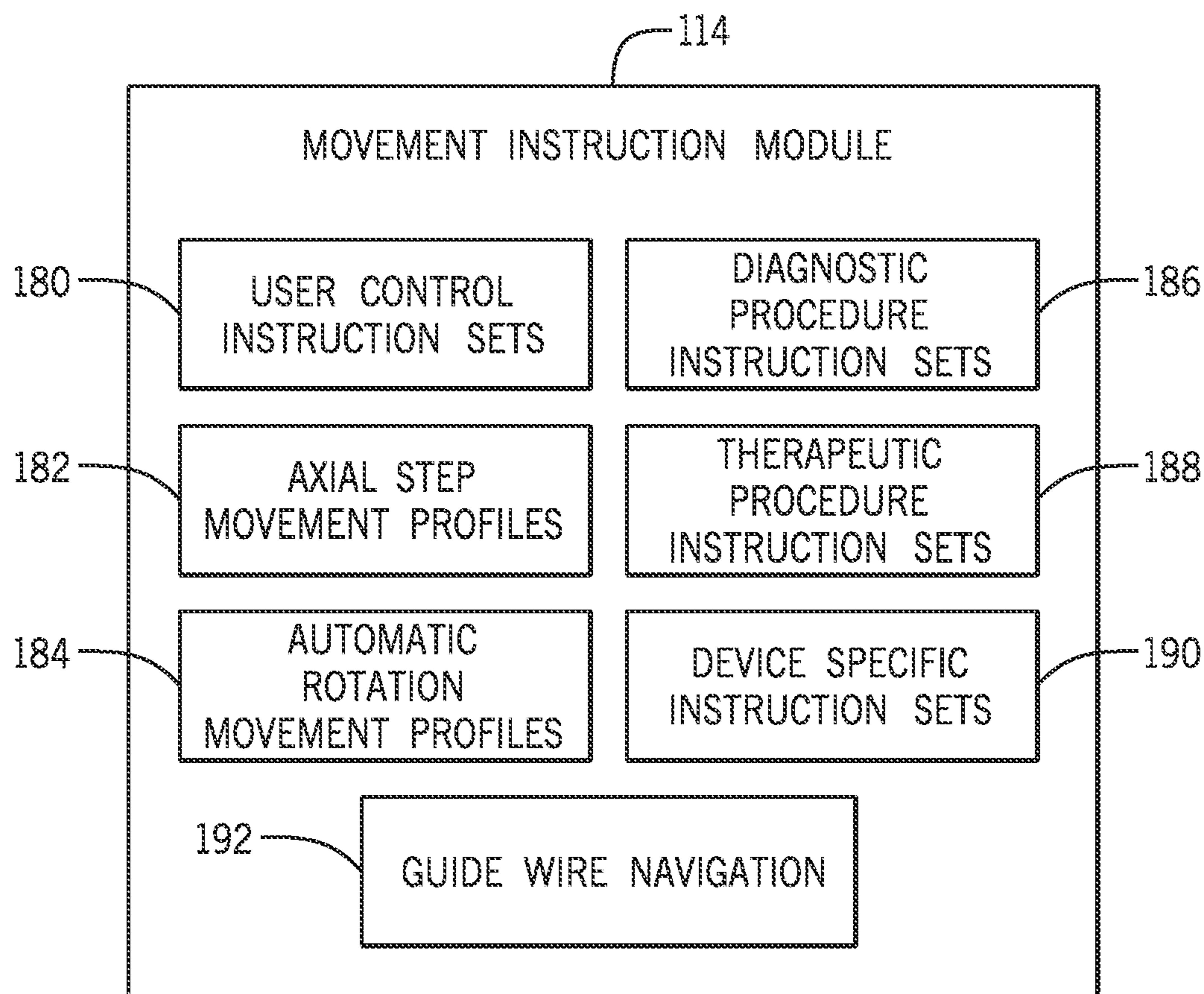


FIG. 5

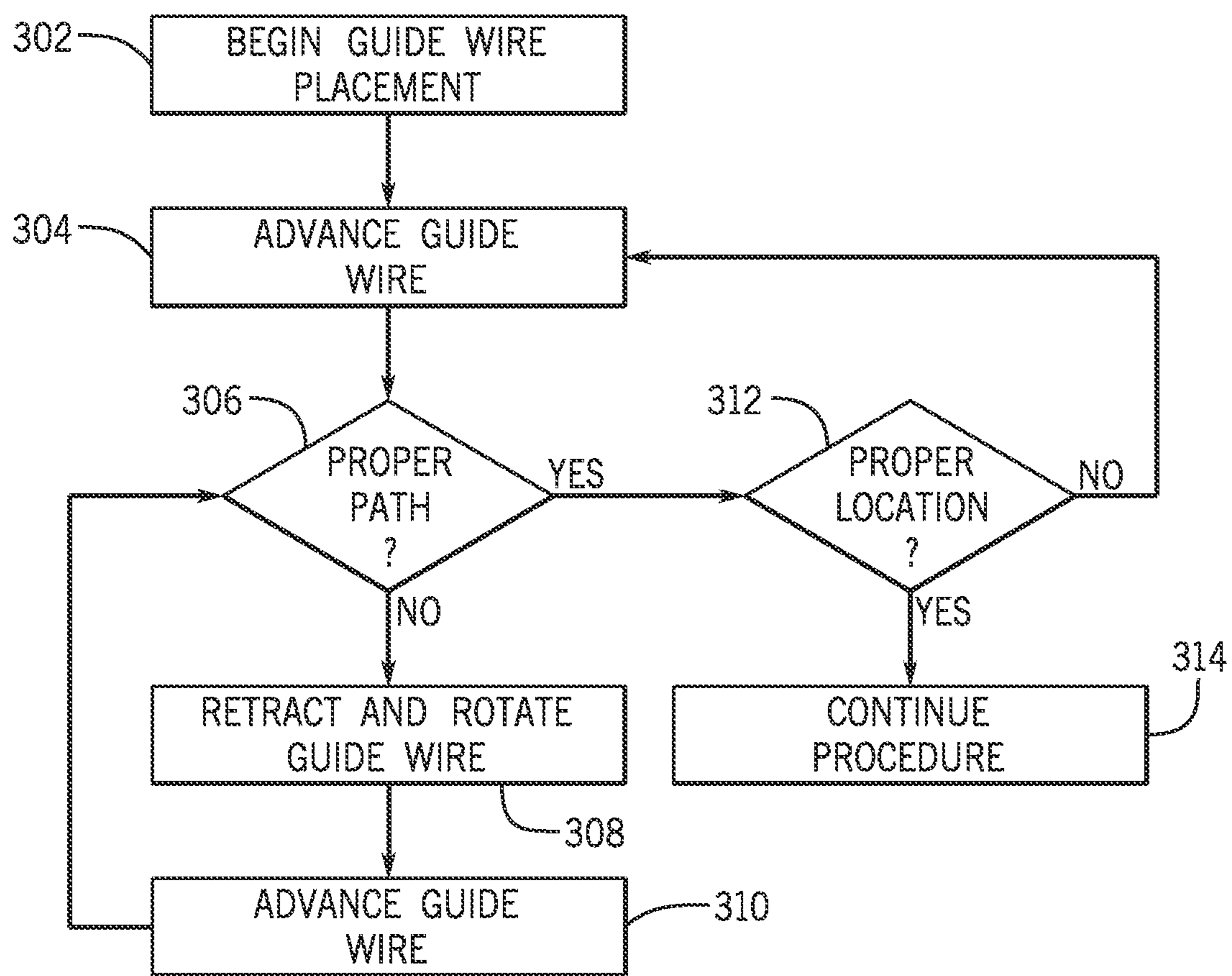


FIG. 6

FIG. 7A

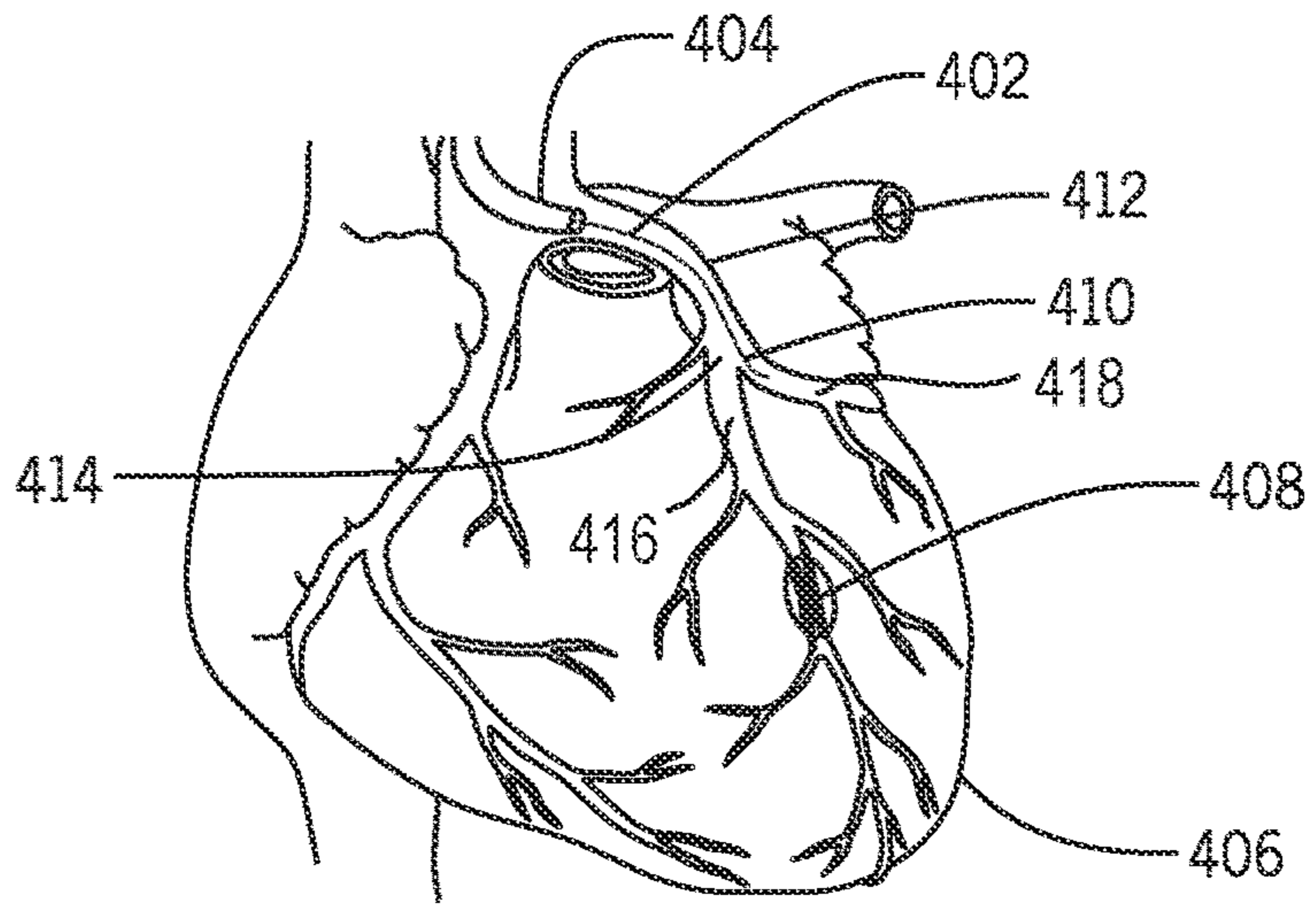


FIG. 7B

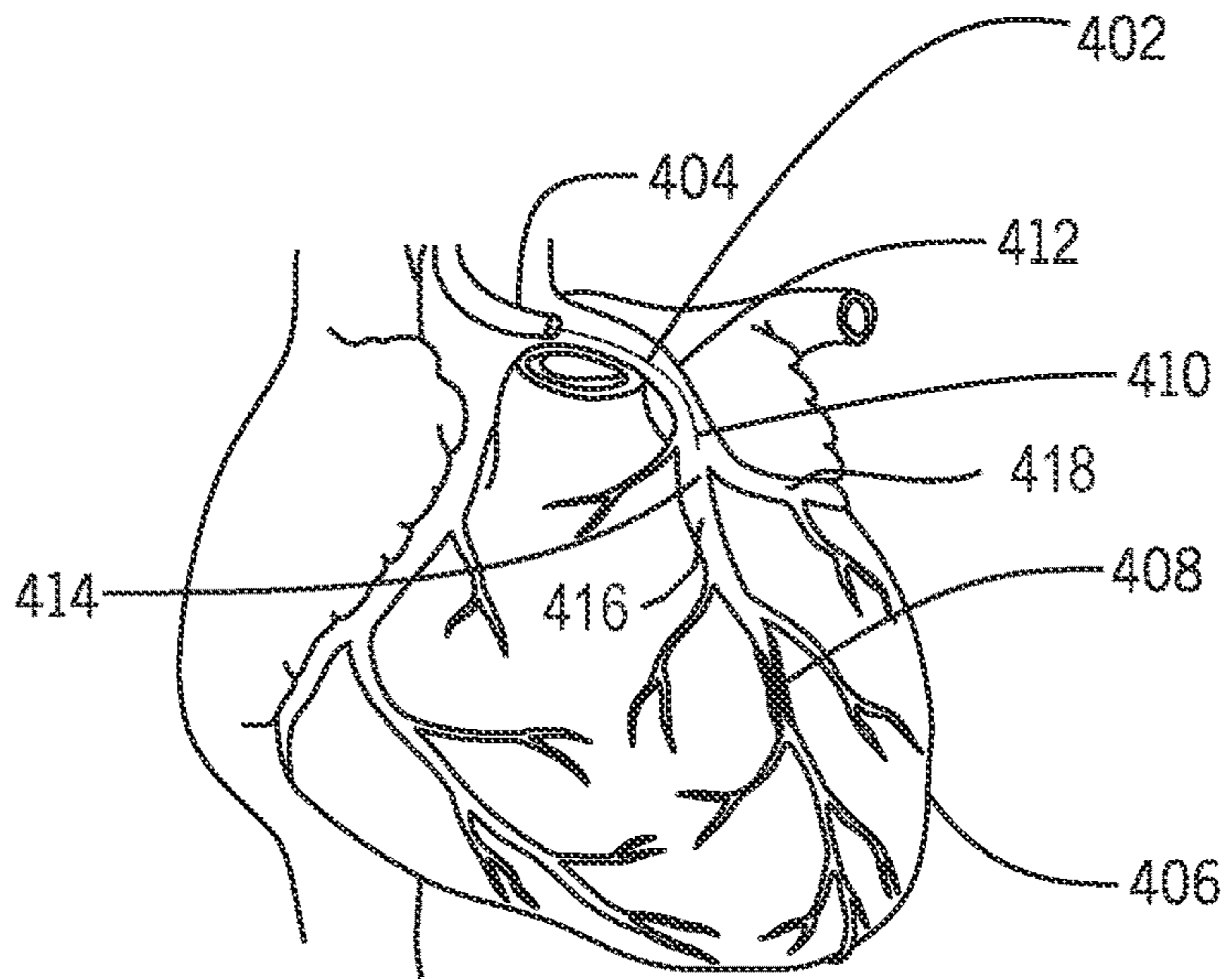
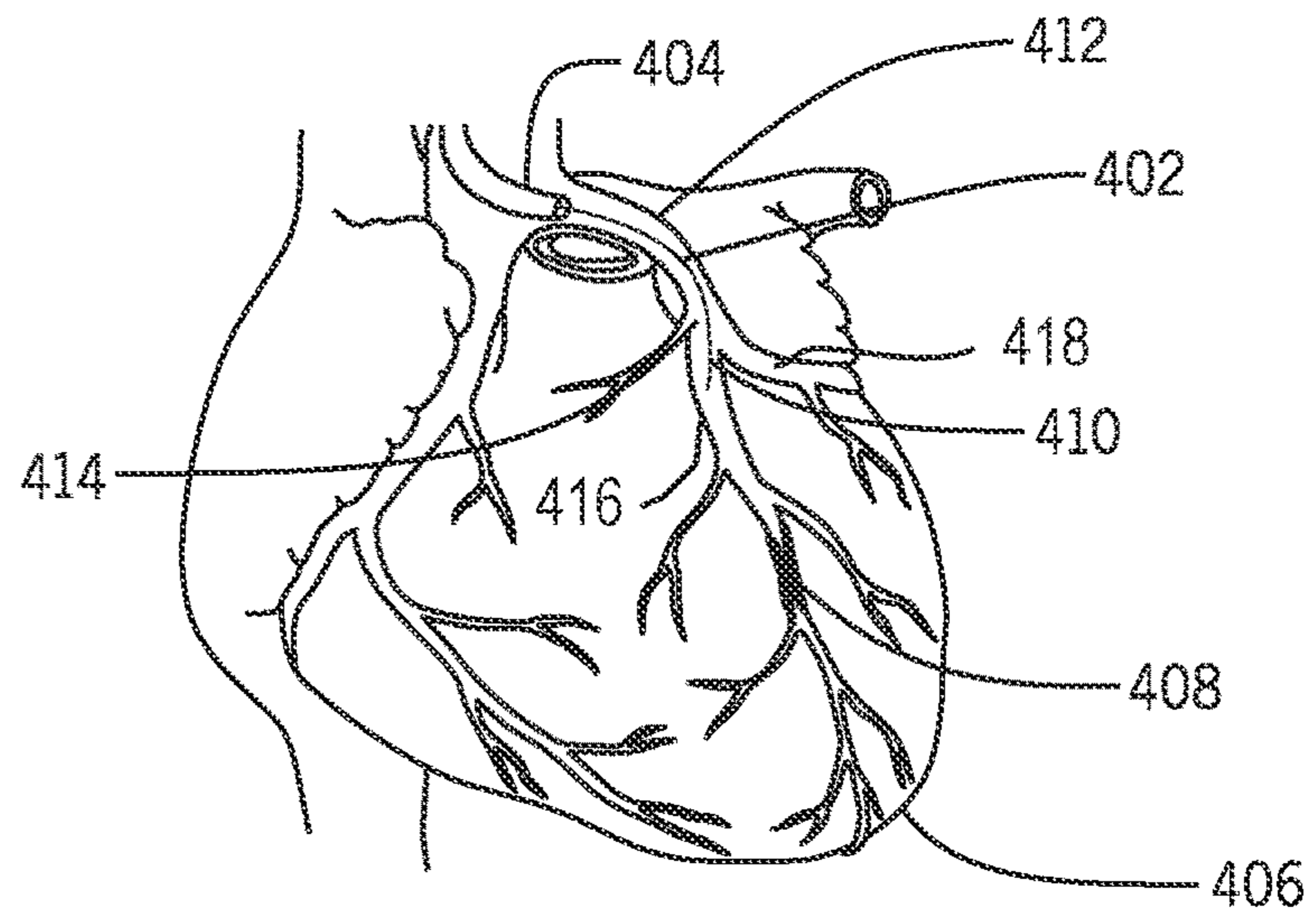


FIG. 7C



SYSTEM AND METHOD FOR NAVIGATING A GUIDE WIRE

CROSS-REFERENCE TO RELATED PATENT APPLICATION

This application is a continuation of U.S. application Ser. No. 15/939,833, filed Mar. 29, 2018 entitled "System and Method for Navigating a Guide Wire" which is a continuation of U.S. application Ser. No. 14/946,117, filed Nov. 19, 2015 entitled "System and Method for Navigating a Guide Wire", now U.S. Pat. No. 9,962,229, which claims the benefit of U.S. Provisional Application No. 62/087,890 filed Dec. 5, 2014 entitled "System And Method For Navigating A Guide Wire" and is a continuation-in-part of U.S. application Ser. No. 13/444,121 filed Apr. 11, 2012 entitled "Catheter System With Percutaneous Device Algorithm" now U.S. Pat. No. 9,220,568, which is a continuation of International Application No. PCT/US2010/052178, filed Oct. 11, 2010, which claims the benefit of U.S. Provisional Application No. 61/250,739 filed Oct. 12, 2009 all of which are incorporated herein by reference in their entirety.

BACKGROUND OF THE INVENTION

The present invention relates generally to the field of catheter systems for performing therapeutic procedures and in particular, to a catheter procedure system and method for navigating a guide wire.

Vascular disease, and in particular cardiovascular disease, may be treated in a variety of ways. Surgery, such as cardiac bypass surgery, is one method for treating cardiovascular disease. However, under certain circumstances, vascular disease may be treated with a catheter based intervention procedure, such as angioplasty. Catheter based intervention procedures are generally considered less invasive than some other types of procedures. If a patient shows symptoms indicative of cardiovascular disease, an image of the patient's heart may be taken to aid in the diagnosis of the patient's disease and to determine an appropriate course of treatment. For certain disease types, such as atherosclerosis, the image of the patient's heart may show a lesion that is blocking one or more coronary arteries. Following the diagnostic procedure, the patient may undergo a catheter based intervention procedure. During one type of intervention procedure, a guide wire is inserted into a blood vessel in the patient's body. The guide wire is then advanced to the desired location, most commonly in one of the heart vessels or elsewhere in the vascular system. A catheter is then slid over the guide wire and moved through the patient's arterial system until the catheter reaches the site of the lesion. In some procedures, the catheter is equipped with a balloon or a stent that when deployed at the site of a lesion allows for increased blood flow through the portion of the coronary artery that is affected by the lesion. In addition to cardiovascular disease, other diseases (e.g., hypertension, etc.) may be treated using catheterization procedures.

For manual insertion of a guide wire, the physician applies torque and axial push force on the proximal end of a guide wire to effect tip direction and axial advancement at the distal end. Robotic catheter systems have been developed that may be used to aid a physician in performing a catheterization procedure such as a percutaneous coronary intervention (PCI). The physician uses a robotic system to precisely steer a coronary guide wire and balloon/stent device in order to, for example, widen an obstructed artery. In order to perform PCI, the distal tip of a guide wire must

be navigated through coronary anatomy past a target lesion. While observing the coronary anatomy using fluoroscopy, the physician manipulates the proximal end of the guide wire in order to direct the distal tip into the appropriate vessels toward the lesion and avoid advancing into side branches. Due to the limitations of fluoroscopy, poor visualization, a lack of depth perception and compliance of the anatomy and the guide wire, it can be difficult to rotate the proximal end of the guide wire and precisely direct its distal tip to the desired location.

It would be desirable to provide a system and method for navigating a guide wire that may reduce the amount of time needed to navigate past a junction point thereby reducing the overall procedure time.

SUMMARY OF THE INVENTION

In accordance with an embodiment, a method for navigating a guide wire during a catheter procedure includes advancing a guide wire through a path using a catheter procedure system, determining if the guide wire is in a desired path based at least on at least one image of a region of interest, rotating the guide wire using the catheter procedure system if the guide wire is not in the desired path, wherein the guide wire is rotated a predetermined amount, retracting the guide wire using the catheter procedure system, repeating the steps of advancing the guide wire and rotating and retracting the guide wire using the catheter procedure system until the guide wire is in the desired path and advancing the guide wire to a desired position using the catheter procedure system.

In accordance with another embodiment, a method for navigating a guide wire during a catheter procedure includes receiving a set of parameters defining a predetermined path, automatically advancing a guide wire through the predetermined path using a catheter procedure system, determining if the guide wire is in the predetermined path based at least on at least one image of a region of interest, rotating the guide wire using the catheter procedure system if the guide wire is not in the predetermined path, wherein the guide wire is rotated a predetermined amount, retracting the guide wire using the catheter procedure system, repeating the steps of advancing the guide wire and retracting and rotating the guide wire using the catheter procedure system until the guide wire is in the predetermined path and advancing the guide wire to a desired position using the catheter procedure system.

In accordance with another embodiment, a catheter procedure system includes a bedside system having a guide wire, a guide wire advance/retract actuator coupled to the guide wire and a guide wire rotate actuator coupled to the guide wire and a workstation coupled to the bedside system including a user interface, at least one display, a controller coupled to the bedside system, the user interface and the at least one display, the controller programmed to advance the guide wire through a path using the guide wire advance/retract actuator, determine if the guide wire is in a desired path based at least on at least one image of a region of interest, rotate the guide wire using the guide wire rotate actuator if the guide wire is not in the desired path, wherein the guide wire is rotated a predetermined amount, retract the guide wire using the guide wire advance/retract actuator, repeat the steps of advancing the guide wire and retracting and rotating the guide wire using guide wire advance/retract actuator and the guide wire rotate actuator until the guide

wire is in the desired path and advance the guide wire to a desired position using the guide wire advance/retract actuator.

In accordance with another embodiment, a catheter procedure system includes a bedside system having a guide wire, a guide wire advance/retract actuator coupled to the guide wire and a guide wire rotate actuator coupled to the guide wire and a workstation coupled to the bedside system including a user interface, at least one display, a controller coupled to the bedside system, the user interface and the at least one display, the controller programmed to receive a set of parameters defining a predetermined path using the user interface, advance the guide wire through the predetermined path using the guide wire advance/retract actuator, determine if the guide wire is in the predetermined path based at least on at least one image of a region of interest, rotate the guide wire using the guide wire rotate actuator if the guide wire is not in the predetermined path, wherein the guide wire is rotated a predetermined amount, retract the guide wire using the guide wire advance/retract actuator, repeat the steps of advancing the guide wire and simultaneously retracting and rotating the guide wire using the guide wire advance/retract actuator and the guide wire rotate actuator until the guide wire is in the predetermined path and advance the guide wire to a desired position using the guide wire advance/retract actuator.

BRIEF DESCRIPTION OF THE DRAWINGS

This application will become more fully understood from the following detailed description, taken in conjunction with the accompanying figures, wherein like reference numerals refer to like elements in which:

FIG. 1 is a perspective view of a catheter procedure system according to an exemplary embodiment;

FIG. 2 is a block diagram of a catheter procedure system according to an exemplary embodiment;

FIG. 3 is a block diagram of a catheter procedure system depicting various actuating mechanisms according to an exemplary embodiment;

FIG. 4 is a block diagram of a controller for controlling a robotic catheter system according to an exemplary embodiment;

FIG. 5 is a block diagram of a movement instruction module according to an exemplary embodiment;

FIG. 6 illustrates a method for navigating a guide wire in accordance with an embodiment; and

FIGS. 7A-7C illustrate an exemplary navigation of a guide wire in accordance with an embodiment.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Before turning to the figures, which illustrate the exemplary embodiments in detail, it should be understood that the present application is not limited to the details or methodology set forth in the description or illustrated in the figures. It should also be understood that the terminology is for the purpose of description only and should not be regarded as limiting.

Referring to FIG. 1, a catheter procedure system 10 is shown. Catheter procedure system 10 may be used to perform catheter based medical procedures (e.g., percutaneous intervention procedures). Percutaneous intervention procedures may include diagnostic catheterization procedures during which one or more catheters are used to aid in the diagnosis of a patient's disease. For example, during one

embodiment of a catheter based diagnostic procedure, a contrast media is injected into one or more coronary arteries through a catheter and an image of the patient's heart is taken. Percutaneous intervention procedures may also include catheter based therapeutic procedures (e.g., balloon angioplasty, stent placement, treatment of peripheral vascular disease, etc.) during which a catheter is used to treat a disease. It should be noted, however, that one skilled in the art would recognize that, certain specific percutaneous intervention devices or components (e.g., type of guide wire, type of catheter, etc.) will be selected based on the type of procedure that is to be performed. Catheter procedure system 10 is capable of performing any number of catheter based medical procedures with minor adjustments to accommodate the specific percutaneous devices to be used in the procedure. In particular, while the embodiments of catheter procedure system 10 described herein are explained primarily in relation to the diagnosis and/or treatment of coronary disease, catheter procedure system 10 may be used to diagnose and/or treat any type of disease or condition amenable to diagnosis and/or treatment via a catheter based procedure. For example, catheter procedure system 10 may be used for the treatment of hypertension utilizing a radiofrequency emitting catheter to deactivate certain nerves that enervate the kidneys to control hypertension.

Catheter procedure system 10 includes lab unit 11 and workstation 14. Catheter procedure system 10 includes a robotic catheter system, shown as bedside system 12, located within lab unit 11 adjacent patient 21. Generally, bedside system 12 may be equipped with the appropriate percutaneous devices (e.g., guide wires, guide catheters, working catheters, catheter balloons, stents, diagnostic catheters, etc.) or other components (e.g., contrast media, medicine, etc.) to allow the user to perform a catheter based medical procedure. A robotic catheter system, such as bedside system 12, may be any system configured to allow a user to perform a catheter-based medical procedure via a robotic system by operating various controls such as the controls located at workstation 14. Bedside system 12 may include any number and/or combination of components to provide bedside system 12 with the functionality described herein. Various embodiments of bedside system 12 are described in detail in P.C.T. International Application No. PCT/US2009/042720, filed May 4, 2009, which is incorporated herein by reference in its entirety.

In one embodiment, bedside system 12 may be equipped to perform a catheter based diagnostic procedure. In this embodiment, bedside system 12 may be equipped with one or more of a variety of catheters for the delivery of contrast media to the coronary arteries. In one embodiment, bedside system 12 may be equipped with a first catheter shaped to deliver contrast media to the coronary arteries on the left side of the heart, a second catheter shaped to deliver contrast media to the coronary arteries on the right side of the heart, and a third catheter shaped to deliver contrast media into the chambers of the heart.

In another embodiment, bedside system 12 may be equipped to perform a catheter based therapeutic procedure. In this embodiment, bedside system 12 may be equipped with a guide catheter, a guide wire, and a working catheter (e.g., a balloon catheter, a stent delivery catheter, ablation catheter, etc.). In one embodiment, bedside system 12 may be equipped with a working catheter that includes a secondary lumen that is threaded over the guide wire during a procedure. In another embodiment, bedside system 12 may be equipped with an over-the-wire working catheter that includes a central lumen that is threaded over the guide wire

during a procedure. In another embodiment, bedside system 12 may be equipped with an intravascular ultrasound (IVUS) catheter. In another embodiment, any of the percutaneous devices of bedside system 12 may be equipped with positional sensors that indicate the position of the component within the body.

Bedside system 12 is in communication with workstation 14, allowing signals generated by the user inputs and/or control system of workstation 14 to be transmitted to bedside system 12 to control the various functions of bedside system 12. Bedside system 12 also may provide feedback signals (e.g., operating conditions, warning signals, error codes, etc.) to workstation 14. Bedside system 12 may be connected to workstation 14 via a communication link 38 that may be a wireless connection, cable connectors, or any other means capable of allowing communication to occur between workstation 14 and bedside system 12.

Workstation 14 includes a user interface 30. User interface 30 includes controls 16. Controls 16 allow the user to control bedside system 12 to perform a catheter based medical procedure. For example, controls 16 may be configured to cause bedside system 12 to perform various tasks using the various percutaneous devices with which bedside system 12 may be equipped (e.g., to advance, retract, or rotate a guide wire, advance, retract, or rotate a working catheter, advance, retract, or rotate a guide catheter, inflate or deflate a balloon located on a catheter, position and/or deploy a stent, inject contrast media into a catheter, inject medicine into a catheter, or to perform any other function that may be performed as part of a catheter based medical procedure, etc.). In some embodiments, one or more of the percutaneous intervention devices may be steerable, and controls 16 may be configured to allow a user to steer one or more steerable percutaneous device. In one such embodiment, bedside system 12 may be equipped with a steerable guide catheter, and controls 16 may also be configured to allow the user located at remote workstation 14 to control the bending of the distal tip of a steerable guide catheter. Further embodiments of catheter system 10 including a steerable guide catheter are disclosed in P.C.T. International Application No. PCT/US2010/27666, filed Mar. 17, 2010, which is incorporated herein by reference in its entirety.

In one embodiment, controls 16 include a touch screen 18, a dedicated guide catheter control 29, a dedicated guide wire control 23, and a dedicated working catheter control 25. In this embodiment, guide wire control 23 is a joystick configured to advance, retract, or rotate a guide wire, working catheter control 25 is a joystick configured to advance, retract, or rotate a working catheter, and guide catheter control 29 is a joystick configured to advance, retract, or rotate a guide catheter. In addition, touch screen 18 may display one or more icons (such as icons 162, 164, and 166) that control movement of one or more percutaneous devices via bedside system 12 or to receive various inputs from the user as discussed below. Controls 16 may also include a balloon or stent control that is configured to inflate or deflate a balloon and/or a stent. Each of the controls may include one or more buttons, joysticks, touch screens, etc., that may be desirable to control the particular component to which the control is dedicated. As discussed in more detail below, catheter procedure system 10 includes a percutaneous device movement algorithm module or movement instruction module 114 that dictates how bedside system 12 responds to a user's manipulation of controls 16 to cause a percutaneous device to move in a particular way.

Controls 16 may include an emergency stop button 31 and a multiplier button 33. When emergency stop button 31 is

pushed a relay is triggered to cut the power supply to bedside system 12. Multiplier button 33 acts to increase or decrease the speed at which the associated component is moved in response to a manipulation of guide catheter control 29, guide wire control 23, and working catheter control 25. For example, if operation of guide wire control 23 advances the guide wire at a rate of 1 mm/sec, pushing multiplier button 33 may cause operation of guide wire control 23 to advance the guide wire at a rate of 2 mm/sec. Multiplier button 33 may be a toggle allowing the multiplier effect to be toggled on and off. In another embodiment, multiplier button 33 must be held down by the user to increase the speed of a component during operation of controls 16.

User interface 30 may include a first monitor 26 and a second monitor 28. First monitor 26 and second monitor 28 may be configured to display information or patient specific data to the user located at workstation 14. For example, first monitor 26 and second monitor 28 may be configured to display image data (e.g., x-ray images, MRI images, CT images, ultrasound images, etc.), hemodynamic data (e.g., blood pressure, heart rate, etc.), patient record information (e.g., medical history, age, weight, etc.). In addition, first monitor 26 and second monitor 28 may be configured to display procedure specific information (e.g., duration of procedure, catheter or guide wire position, volume of medicine or contrast agent delivered, etc.). In one embodiment, the user may interact with or select various icons or information displayed on monitors 26 and 28 using a user input device or control (e.g., a mouse). Monitor 26 and monitor 28 may be configured to display information regarding the position and/or bend of the distal tip of a steerable guide catheter. Further, monitor 26 and monitor 28 may be configured to display information to provide the functionalities associated with the various modules of controller 40 discussed below. In another embodiment, user interface 30 includes a single screen of sufficient size to display one or more of the display components and/or touch screen components discussed herein.

Catheter procedure system 10 also includes an imaging system 32 located within lab unit 11. Imaging system 32 may be any medical imaging system that may be used in conjunction with a catheter based medical procedure (e.g., non-digital x-ray, digital x-ray, CT, MRI, ultrasound, etc.). In an exemplary embodiment, imaging system 32 is a digital x-ray imaging device that is in communication with workstation 14. As shown in FIG. 1, imaging system 32 may include a C-arm that allows imaging system 32 to partially or completely rotate around patient 21 in order to obtain images at different angular positions relative to patient 21 (e.g., sagittal views, caudal views, cranio-caudal views, etc.).

Imaging system 32 is configured to take x-ray images of the appropriate area of patient 21 during a particular procedure. For example, imaging system 32 may be configured to take one or more x-ray images of the heart to diagnose a heart condition. Imaging system 32 may also be configured to take one or more x-ray images during a catheter based medical procedure (e.g., real-time images) to assist the user of workstation 14 to properly position a guide wire, guide catheter, working catheter, stent, etc. during the procedure. The image or images may be displayed on first monitor 26 and/or second monitor 28.

In addition, the user of workstation 14 may be able to control the angular position of imaging system 32 relative to the patient to obtain and display various views of the patient's heart on first monitor 26 and/or second monitor 28. Displaying different views at different portions of the pro-

cedure may aid the user of workstation **14** properly move and position the percutaneous devices within the 3D geometry of the patient's heart. For example, displaying the proper view during a procedure may allow the user to view a patient's vascular system from the proper angle to ensure that the distal tip of a steerable guide catheter is bent in the proper way to ensure the catheter is moved as intended. In addition, displaying different views at different portions of a procedure may aid the user in selecting the appropriate instruction set of movement instruction module **114** discussed below. In an exemplary embodiment, imaging system **32** may be any 3D imaging modality of the past, present, or future, such as an x-ray based computed tomography (CT) imaging device, a magnetic resonance imaging device, a 3D ultrasound imaging device, etc. In this embodiment, the image of the patient's heart that is displayed during a procedure may be a 3D image. In addition, controls **16** may also be configured to allow the user positioned at workstation **14** to control various functions of imaging system **32** (e.g., image capture, magnification, collimation, c-arm positioning, etc.).

Referring to FIG. **2**, a block diagram of catheter procedure system **10** is shown according to an exemplary embodiment. Catheter procedure system **10** may include a control system, shown as controller **40**. As shown in FIG. **2**, controller **40** may be part of workstation **14**. Controller **40** is in communication with one or more bedside systems **12**, controls **16**, monitors **26** and **28**, imaging system **32**, and patient sensors **35** (e.g., electrocardiogram ("ECG") devices, electroencephalogram ("EEG") devices, blood pressure monitors, temperature monitors, heart rate monitors, respiratory monitors, etc.). In addition, controller **40** may be in communication with a hospital data management system or hospital network **34**, one or more additional output devices **36** (e.g., printer, disk drive, cd/dvd writer, etc.), and a hospital inventory management system **37**.

Communication between the various components of catheter procedure system **10** may be accomplished via communication links **38**. Communication links **38** may be dedicated wires or wireless connections. Communication links **38** may also represent communication over a network. Catheter procedure system **10** may be connected or configured to include any other systems and/or devices not explicitly shown. For example, catheter procedure system **10** may include IVUS systems, image processing engines, data storage and archive systems, automatic balloon and/or stent inflation systems, contrast media and/or medicine injection systems, medicine tracking and/or logging systems, user logs, encryption systems, systems to restrict access or use of catheter procedure system **10**, robotic catheter systems of the past, present, or future, etc. Further embodiments of catheter procedure system **10** including inflation and/or contrast media injection systems are disclosed in P.C.T. International Application No. PCT/US2009/67540, filed Dec. 10, 2009, which is incorporated herein by reference in its entirety.

Referring to FIG. **3**, a block diagram of an embodiment of catheter procedure system **10** is shown according to an exemplary embodiment. Catheter procedure system **10** may include various actuating mechanisms that move an associated percutaneous device in response to a user's manipulation of controls **16**. In the embodiment shown, catheter procedure system **10** includes a guide wire actuating mechanism **50**, a working catheter actuating mechanism **52**, and a guide catheter actuating mechanism **54**. In other embodiments, catheter procedure system **10** may include an actuating mechanism for inflating an angioplasty or stent delivery balloon and an actuating mechanism for delivering

contrast agent. In the embodiment shown, guide wire actuating mechanism **50** and working catheter actuating mechanism **52** are incorporated within cassette **56** which is coupled to a base of bedside system **12**. Additional embodiments of bedside system **12** and cassette **56** are described in detail in P.C.T. International Application No. PCT/US2009/042720, filed May 4, 2009, which is incorporated herein by reference in its entirety. Further embodiments of catheter procedure system **10** are described in detail in P.C.T. International Application No. PCT/US2010/27666, filed Mar. 17, 2010, and in P.C.T. International Application No. PCT/US2009/67540, filed Dec. 10, 2009, both of which are incorporated herein by reference in their entireties.

Guide wire actuating mechanism **50** is coupled to guide wire **58** such that guide wire actuating mechanism **50** is able to cause guide wire **58** to advance, retract, and rotate. Working catheter actuating mechanism **52** is coupled to working catheter **60** such that working catheter actuating mechanism **52** is able to cause working catheter **60** to advance, retract, and rotate. Connector **62** couples guide catheter **64** to guide catheter actuating mechanism **54** such that guide catheter actuating mechanism **54** is able to cause guide catheter **64** to advance, retract, and rotate. In various embodiments, guide wire actuating mechanism **50**, working catheter actuating mechanism **52**, and guide catheter actuating mechanism may each include an engagement structure (e.g., one or more pairs of pinch wheels) suitable for engaging the respective percutaneous device such that the actuating mechanism is able to impart axial and/or rotational movement to the percutaneous device.

A Y-connector **66** is coupled to guide catheter actuating mechanism **54** via connector **68**. In various embodiments, connector **68** may be a component separate from both Y-connector **66** and guide catheter actuating mechanism **54**. In other embodiments, connector **68** may be part of (e.g., integral with) Y-connector **66** or part of actuating mechanism **54**. In the embodiment shown, Y-connector **66** is also connected to cassette **56**.

In one embodiment, Y-connector **66** includes a first leg, a second leg, and a third leg. The first leg of the Y-connector is connected to or in communication with the internal lumen of guide catheter **64**. The second leg is angled away from the longitudinal axis of guide catheter **64**. The second leg provides a port for the injection of fluids (e.g., contrast media, medicine, etc.) into the lumen of guide catheter **64**. The third leg of Y-connector **66** is coupled to a cassette **56** and receives both guide wire **58** and working catheter **60**. Thus, by this arrangement, guide wire **58** and working catheter **60** are inserted through Y-connector **66** into the internal lumen of guide catheter **64**.

Guide wire actuating mechanism **50** includes a rotate actuator **70** and an advance/retract actuator **72**. Rotate actuator **70** is configured to cause rotation of guide wire **58** about its longitudinal axis. Advance/retract actuator **72** is configured to advance and/or retract guide wire **58** (i.e., to advance and/or retract along the longitudinal axis of the guide wire) within patient **21**. Working catheter actuating mechanism **52** includes a rotate actuator **74** and an advance/retract actuator **76**. Rotate actuator **74** is configured to cause rotation of working catheter **60** about its longitudinal axis. Advance/retract actuator **76** is configured to advance and/or retract working catheter **60** (i.e., to advance and/or retract along the longitudinal axis of the working catheter) within patient **21**. Guide catheter actuating mechanism **54** includes a rotate actuator **78**, an advance/retract actuator **80**, and a bend actuator **82**. Rotate actuator **78** is configured to cause rotation of guide catheter **64** about its longitudinal axis.

Advance/retract actuator **80** is configured to advance and/or retract guide catheter **64** (i.e., to advance and/or retract along the longitudinal axis of the guide catheter) within patient **21**. In some embodiments, guide catheter **64** may include one or more bend control elements that allow the user to cause bending of the distal tip of guide catheter **64**. In such an embodiment, bend actuator **82** causes the distal tip of guide catheter **64** to bend in response to a user's manipulation of controls **16**.

As shown in the block diagram of FIG. **3**, controls **16** and controller **40** located at workstation **14** are communicably coupled to various portions of bedside system **12** to allow the user and/or control system to control movement of guide wire **58**, working catheter **60** and guide catheter **64** and any other percutaneous devices that bedside system **12** is equipped with. In the embodiment shown, controls **16** and controller **40** are coupled to guide catheter actuating mechanism **54** to allow the user to move guide catheter **64**. In addition, controls **16** and controller **40** are coupled to cassette **56** to allow the user to control guide wire **58** via guide wire actuating mechanism **50** and to control working catheter **60** via working catheter actuating mechanism **52**. Control signals **116** generated by the controls and controller at workstation **14** are communicated to bedside system **12** to control movement of percutaneous devices discussed herein.

Referring to FIG. **4**, a block diagram of controller **40** is shown according to an exemplary embodiment. Controller **40** may generally be an electronic control unit suitable to provide catheter procedure system **10** with the various functionalities described herein. For example, controller **40** may be an embedded system, a dedicated circuit, a general purpose system programmed with the functionality described herein, etc. Controller **40** includes a processing circuit **90**, memory **92**, communication module or subsystem **94**, communication interface **96**, procedure control module or subsystem **98**, simulation module or subsystem **100**, assist control module or subsystem **102**, mode selection module or subsystem **104**, inventory module or subsystem **106**, GUI module or subsystem **108**, data storage module or subsystem **110**, and record module or subsystem **112**.

Processing circuit **90** may be a general purpose processor, an application specific processor (ASIC), a circuit containing one or more processing components, a group of distributed processing components, a group of distributed computers configured for processing, etc., configured provide the functionality of module or subsystem components **94**, **98-114**. Memory **92** (e.g., memory unit, memory device, storage device, etc.) may be one or more devices for storing data and/or computer code for completing and/or facilitating the various processes described in the present disclosure. Memory **92** may include volatile memory and/or non-volatile memory. Memory **92** may include database components, object code components, script components, and/or any other type of information structure for supporting the various activities described in the present disclosure.

According to an exemplary embodiment, any distributed and/or local memory device of the past, present, or future may be utilized with the systems and methods of this disclosure. According to an exemplary embodiment, memory **92** is communicably connected to processing circuit **90** and module components **94**, **98-114** (e.g., via a circuit or any other wired, wireless, or network connection) and includes computer code for executing one or more processes described herein. A single memory unit may include a variety of individual memory devices, chips, disks, and/or other storage structures or systems.

Module or subsystem components **94**, **98-114** may be computer code (e.g., object code, program code, compiled code, script code, executable code, or any combination thereof), hardware, software, or any combination thereof, for conducting each module's respective functions. Module components **94**, **98-114** may be stored in memory **92**, or in one or more local, distributed, and/or remote memory units configured to be in communication with processing circuit **90** or another suitable processing system.

Communication interface **96** includes one or more component for communicably coupling controller **40** to the other components of catheter procedure system **10** via communication links **38**. Communication interface **96** may include one or more jacks or other hardware for physically coupling communication links **38** to controller **40**, an analog to digital converter, a digital to analog converter, signal processing circuitry, and/or other suitable components. Communication interface **96** may include hardware configured to connect controller **40** with the other components of catheter procedure system **10** via wireless connections. Communication module **94** is configured to support the communication activities of controller **40** (e.g., negotiating connections, communication via standard or proprietary protocols, etc.).

Data storage module **110** is configured to support the storage and retrieval of information by controller **40**. In one embodiment, data storage module **110** is a database for storing patient specific data, including image data. In another embodiment, data storage module **110** may be located on hospital network **34**. Data storage module **110** and/or communication module **94** may also be configured to import and/or export patient specific data from hospital network **34** for use by controller **40**.

Controller **40** also includes a procedure control module **98** configured to support the control of bedside system **12** during a catheter based medical procedure. Procedure control module **98** allows the user to operate bedside system **12** by manipulating controls **16**. To provide this control, procedure control module **98** is in communication with a percutaneous device movement algorithm or movement instruction module **114**. Movement instruction module **114** includes one or more movement algorithms or instruction sets (e.g., a library of instruction sets) that dictate how bedside system **12** operates in response to a user's manipulation of controls **16** to produce movement of one or more of the percutaneous devices (e.g., guide wire, working catheter, guide catheter, etc.) that bedside system **12** is equipped with. In various embodiments, procedure control module **98** is configured to generate one or more control signals **116** based upon the user's manipulation of controls **16** and based upon one or more active set of movement instructions provided by movement instruction module **114**. Control signals generated by procedure control module **98** are communicated from controller **40** to the appropriate actuator or actuators of bedside system **12**. The control signals control the appropriate actuators to cause movement of a percutaneous device in accordance with the manipulation of controls **16** by the user and with the active instruction set of movement instruction module **114**. In this manner, movement of the percutaneous device may be controlled from workstation **14**. Procedure control module **98** may also cause data appropriate for a particular procedure to be displayed on monitors **26** and **28**. Procedure control module **98** may also cause various icons (e.g., icons **162**, **164**, **166**, etc.) to be displayed on touch screen **18** that the user may interact with to control the use of bedside system **12**.

Referring to FIG. **5**, movement instruction module **114** is depicted according to an exemplary embodiment. In one

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embodiment, movement instruction module **114** is configured to allow the user to specifically control each movement of a percutaneous device via bedside system **12**. In this embodiment, movement instruction module **114** includes a user control instruction set **180** that includes device movement instructions to cause bedside system **12** to move (e.g., advance, retract, rotate, etc.) the percutaneous device in a predefined, set manner (e.g., at a set rate, in a set direction, etc.) in response to a particular input received by controls **16**.

For example, user control instruction set **180** of movement instruction module **114** may be configured such that when guide wire control **23** is actuated, bedside system **12** causes the guide wire to advance, retract or rotate at a set rate. Thus, in this embodiment, movement instruction module **114** is configured to allow the user to control the rate and direction of movement of a percutaneous device based on the user's interaction with controls **16**. Thus, for certain procedures, the user may select or activate user control instruction set **180** when the user desires to directly control every movement of the percutaneous device by manipulating controls **16**.

In one specific embodiment, the movement rate of a percutaneous device caused by bedside system **12** is proportional to the amount of displacement of the control. For example, where controls **23**, **25** and **29** are joystick controls, user control instruction set **180** may be configured such that the movement rate of a percutaneous device caused by bedside system **12** is proportional to the degree of displacement of the joystick from the resting position. Further, in this embodiment, the direction of movement (e.g., advancement or retraction) of the percutaneous device caused by bedside system **12** is based on the direction of displacement of the joystick from the resting position.

As discussed above, controls **16** may include a multiplier button **33**. Movement instruction module **114** may include a first set of instructions that is active or operative when multiplier button **33** is not activated and a second set of instructions that is operative when multiplier button **33** is activated. In this embodiment, the second set of instructions is configured to cause a percutaneous device to be moved faster by bedside system **12** than it would be moved under the control of the first set of instructions. Thus, when the user presses multiplier button **33**, the second set of instructions of movement instruction module **114** is activated causing an increase in the rate of movement of a percutaneous device that results from a particular operation of controls **16**. For example, if the first set of instructions of movement instruction module **114** dictates a 1 mm per second rate of advancement of the working catheter when control **16** is fully actuated (e.g., full displacement of a joystick control), then the second set of instructions of movement instruction module **114** may cause a 2 mm per second rate of advancement of the working catheter when control **16** is fully actuated.

In various embodiments, movement instruction module **114** may include various sets of instructions to facilitate the performance of certain movements of percutaneous devices via bedside system **12** without the user having to manually manipulate controls **16** in a series of complicated movements to generate a particular type of movement by the percutaneous device. In these embodiments, a user may select or activate a particular movement instruction set that defines a movement profile, and when controls **16** are manipulated by the user, the percutaneous device is moved in accordance with the movement profile. Thus, movement instruction module **114** may allow a particular movement of a percutaneous device associated with the activated instruc-

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tion set to be performed consistently in each procedure. The movement profile needed to perform a particular procedure may depend on factors such as, the type of condition being treated (e.g., a chronic total occlusion (CTO), partial occlusion, etc.), the location of the condition being treated (e.g., coronary arteries, peripheral arteries, etc.), the geometry of the area being treated, the particular type (e.g., make, model, size, etc.) of percutaneous device being used, etc.

In one embodiment, movement instruction module **114** may include an axial step movement profile instruction set **182** that is configured to cause bedside system **12** to move a percutaneous device in series of small axially steps or pulses when a user operates controls **16** to cause advancement of the percutaneous device. In such an embodiment, axial step movement profile instruction set **182** of movement instruction module **114** may specify a step distance (i.e., a distance parameter of the step, e.g., 0.2 mm, 0.4 mm, 0.8 mm, 1 mm, 1.5 mm, 2 mm, etc.), a step duration (i.e., the length of time it takes the device to move the step distance, e.g., 0.05 sec, 0.1 sec, 0.3 sec, 0.5 sec, 1 sec, etc.), and a rest duration (i.e., the length of time between steps, e.g., 0.05 sec, 0.1 sec, 0.3 sec, 0.5 sec, 1 sec, etc.). Such pulsed movement may be used to allow a percutaneous device to traverse a CTO. In this embodiment, advancement of the percutaneous device along its longitudinal axis occurs in a series of pulsed axial steps defined by the step distance, step duration, and rest duration.

In another embodiment, axial step movement profile instruction set **182** of movement instruction module **114** may include a movement profile that is configured to cause bedside system **12** to intersperse one or more retract pulses (i.e., pulses the move the device in a direction opposite of the direction of advancement) with the axial advance pulses when a user operates controls **16** to cause net advancement of a percutaneous device. In one embodiment, movement instruction module **114** may be configured to cause bedside system **12** to move a percutaneous device in a set of forward pulses that is followed by one or more retract pulses, which is then followed by a second set of forward pulses, and so on, while the user operates controls **16** to cause advancement of the percutaneous device. To ensure net forward progress utilizing such a movement profile, the instruction set ensures that the distance traveled during each set of forward pulses is greater than the distance traveled during the retract pulses. The retract pulse may allow the percutaneous device to disengage from a structure (e.g., lesion, vessel wall, etc.) prior to further advancement. In various embodiments, movement instruction module **114** may be configured to cause pulsed movement of any percutaneous device with which bedside system **12** is equipped, including the guide wire, working catheter, and guide catheter.

In another embodiment, movement instruction module **114** may include an automatic rotation movement profile instruction set **184** that is configured to cause bedside system **12** to rotate the percutaneous device at a set rate as the percutaneous device is advanced and/or retracted in response to the user's operation of controls **16** to cause advancement/retraction of a percutaneous device. In such an embodiment, automatic rotation movement profile instruction set **184** of movement instruction module **114** may specify an amount of rotation experienced by the percutaneous device as the percutaneous device is advanced or retracted (i.e., a rotation rate). The rotation rate may be specified in terms of degrees of rotation per unit of axial distance traveled (e.g., 360 degrees of rotation for each 2 mm traveled, etc.) or may be specified in terms of degrees of rotation per unit of time of axial travel (e.g., 360 degrees

of rotation for each 5 seconds of axial travel). This embodiment allows the user to perform a drilling or corkscrew action with the percutaneous device without having to manually operate controls **16** to cause both axial movement and rotation. In various embodiments, movement instruction module **114** may include instructions to cause such movement of any device with which bedside system **12** is equipped, including the guide wire, working catheter, and guide catheter.

In various embodiments, controller **40** is configured to allow a user to set or select one more of the parameters associated with a particular movement profile. For example, a user may input or select the desired step distance, step duration, rest duration, rotation rate, etc., for the movement profiles discussed above. In these embodiments, controls **16** may include at least one user input device or a control (e.g., touch screen icons **162**, **164**, **166**, keyboard, etc.) that allows the user to input the parameters associated with a movement profile.

In one embodiment, one or more user input devices of controls **16** may be a dedicated user input device that is associated with one of the movement instruction sets of movement instruction module **114** such that operation of the associated user input device itself causes bedside system **12** to move the percutaneous device in accordance with the movement profile. In one embodiment, procedure control module **98** may be configured to display one or more icons (e.g., icons **162**, **164**, **166**, etc.) on touch screen **18** that is associated with a set of movement instructions (e.g., profiles **182** and **184**). When the user operates or touches one of the touch screen icons associated with a movement instruction set, bedside system **12** is controlled to move a percutaneous device in accordance with the instruction set associated with the touch screen icon. In one embodiment, certain user input devices of controls **16** (e.g., one or more joysticks) may allow for total or specific control of movement of the percutaneous device by the user, and manipulation of the dedicated touch screen icon causes bedside system to advance the percutaneous device in accordance with an associated axial step movement profile or rotation movement profile.

In one embodiment, bedside system **12** may be equipped with a steerable guide catheter **64** that may be steered by bending the distal tip via bend actuator **82** in response to a user's manipulation of controls **16**. In this embodiment, the distal tip of steerable guide catheter **64** may be bent to a particular shape or angle to position guide catheter **64** properly to perform a particular procedure, and movement instruction module **114** may include one or more instruction sets that define a movement profile configured to cause bedside system **12** to move the distal tip of guide catheter **64** to the desired position. In one embodiment, procedure control module **98** may be configured to display several icons (such as icons **162**, **164**, or **166**) on touch screen **18** each indicating a different bend angle or bend shape (e.g., a button for a 30 degree bend, a button for a 40 degree bend, a button for the Judkins Left 4 bend, a button for the Judkins Right 4 bend, etc.), and when the user pushes the button for a particular degree bend or bend shape, the instruction set of movement instruction module **114** associated with the selected icon is executed causing the distal tip of guide catheter **64** to move to the bend angle or bend shape associated with the selected icon.

In another embodiment, movement instruction module **114** may include sets of instructions specific to various types of catheter based procedures that may be performed using bedside system **12**. For example, movement instruction

module **114** may include one set of instructions that will be executed if bedside system **12** is being used to perform a diagnostic catheterization procedure, shown as diagnostic procedure instruction set **186**, and another set of instructions that will be executed if bedside system **12** is being used to perform a therapeutic catheter procedure, shown as therapeutic procedure instruction set **188**. In this embodiment, controls **16** may include at least one user input device (e.g., touch screen icons **162**, **164**, **166**) that allows the user to select whether catheter procedure system **10** is going to be used for a diagnostic or therapeutic procedure. In this embodiment, a user input device (e.g., touch screen icon **162**, **164**, **166**) of controls **16** may be associated with a diagnostic procedure and another user input device may be associated with a therapeutic procedure, and selection or operation of the associated user input device by the user activates diagnostic procedure instruction set **186** or therapeutic procedure instruction set **188**.

In addition, diagnostic procedure instruction set **186** or therapeutic procedure instruction set **188** may include various subsets of instructions for various types of diagnostic or therapeutic procedures that may be performed using bedside system **12**. In one such embodiment, a user input device (e.g., touch screen icon **162**, **164**, **166**) of controls **16** may be associated with a specific type of therapeutic procedure, and selection or operation of the associated user input device activates the appropriate instruction set of therapeutic procedure instruction set **188** that is related to the specific type of therapeutic procedure to be performed. For example, therapeutic procedure instruction set **188** may include a first instruction set associated with a stent placement procedure, a second instruction set associated with an angioplasty procedure, a third instruction set associated with an ablation procedure, etc. Thus, in this embodiment, the user will select the type of therapeutic procedure that is to be performed via the associated user input device, and the instruction subset of therapeutic procedure instruction set **188** for the selected type of therapeutic procedure will be activated.

In other embodiments, movement instruction module **114** may include sets of instructions specific to various types of percutaneous devices that may be used with bedside system **12**, shown as device specific instruction sets **190**. For example, device specific instruction sets **190** may include a set of instructions for each different type, make and/or model of percutaneous devices that may be used with bedside system **12**. In such an embodiment, the instruction set for a particular type, make or model of percutaneous device may account for the properties of the device (e.g., weight, diameter, surface friction, rigidity, etc.) to ensure that the percutaneous device is moved as expected by bedside system **12**. In addition, the instruction set for a particular percutaneous device may be based on the type of device being controlled by bedside system **12** (e.g., a guide wire, guide catheter, a working catheter, an angioplasty balloon, a stent, ablation catheter, imaging catheter, etc.).

Some percutaneous devices are designed to be moved or controlled in a particular way during treatment of a condition. Device specific instruction sets **190** may include one or more instruction sets to cause bedside system **12** to move such a percutaneous devices in a manner consistent with its design. For example, in one embodiment, device specific instruction sets **190** may include one or more instruction sets to allow bedside system **12** to control a device specially designed to traverse a chronic total occlusion (e.g., the CrossBoss CTO Catheter manufactured by BridgePoint Medical). In this embodiment, movement instruction mod-

ule **114** includes an instruction set that allows bedside system **12** to rotate the CrossBoss CTO Catheter at its specified speed.

In another exemplary embodiment, device specific instruction sets **190** may include one or more instruction sets to allow bedside system **12** to control the Symplicity Catheter manufactured by Ardian, Inc. for the treatment of hypertension. The Symplicity Catheter emits low-power radiofrequency energy to deactivate certain renal nerves from within the renal artery to treat hypertension. In this embodiment, movement instruction module **114** includes an instruction set to cause the Symplicity Catheter to retract a certain distance, to rotate a certain amount, and to emit a pulse of radiofrequency energy following rotation and retraction. In this embodiment the retract distance and the rotation amount are determined to position the Symplicity Catheter in the proper locations to deactivate the proper number of renal nerves to treat hypertension.

Controller **40** also includes simulation module or subsystem **100**, assist module or subsystem **102**, mode selection module or subsystem **104**, inventory module or subsystem **106**, GUI module or subsystem **108**, data storage module or subsystem **110**, and record module or subsystem **112**. Generally, simulation module **100** is configured to run a simulated catheterization procedure based upon stored vascular image data and also based upon a user's manipulation of controls **16**. Generally, assist module **102** is configured to provide information to the user located at workstation **14** during a real and/or simulated catheterization procedure to assist the user with the performance of the procedure. Specific embodiments of controller **40**, including specific embodiments of simulation module **100**, and assist module **102**, are described in detail in P.C.T. International Application No. PCT/US2009/055318, filed Aug. 28, 2009, which is incorporated herein by reference in its entirety. Other specific embodiments of controller **40**, including specific embodiments of GUI module **108**, are described in P.C.T. International Application No. PCT/US2009/055320, filed Aug. 28, 2009, which is incorporated herein by reference in its entirety.

Movement instruction module **114** has been described as including various instructions sets in various exemplary embodiments as discussed above. However, it should be understood that movement instruction module **114** may include any combination of one or more of the instruction sets discussed above. In any embodiment in which movement instruction module **114** includes more than one instruction set, controller **40** may be configured to select one or more proper instruction set to be activated for a particular procedure either automatically or based on a received user input.

In various embodiments, controller **40** may be configured to allow the user of controls **16** to choose which instruction set or sets of movement instruction module **114** to activate for a particular procedure. In one such embodiment, one or more user input device (e.g., touch screen icon **162**, **164**, **166**, a button, switch, etc.) of controls **16** may be associated with a particular movement instruction set, and selection or operation of the associated user input device activates the instruction set of movement instruction module **114** related to the desired movement parameter or movement profile. Then, with one of the instruction sets activated via operation of the associated user input device, the percutaneous device is moved in accordance with the activated movement instruction set as the user manipulates controls **16** (e.g., a joystick).

In one embodiment, procedure control module **98** may display information associated with one or more of the available instruction sets of movement instruction module **114** from which the user may chose. For example, a list of available instruction sets (e.g., instruction set for pulsed axial movement, instruction set for corkscrew motion, instruction sets for different percutaneous devices, etc.) may be displayed on a display device. In this embodiment, the user may then select the desired instruction set from the list to activate that instruction set using a device such as a mouse or touch screen. When an instruction set of movement instruction module **114** is activated, control signal **116** and the resulting movement of percutaneous device is based upon the user's manipulation of controls **16** and based upon the activated instruction set. In one embodiment, controller **40** is configured to display a separate touch screen icon associated with each movement instruction set of movement instruction module **114**. In another embodiment, each available instruction set may be displayed as a list (e.g., a drop-down menu) allowing the user to select the desired instruction set via an input device such as a mouse.

In other embodiments, controller **40** may be configured such that one or more movement instruction set of movement instruction module **114** may be active at one time. In this embodiment, the user may activate any combination of one or more instruction sets of movement instruction module **114** via the associated user input devices. In one embodiment, the user may select more than one instruction set from the list of available instruction sets. For example, the user may activate both the axial step movement profile and the rotational movement profile at the same time, such that operation of controls **16** causes bedside system **12** to move the percutaneous device both for rotation and pulsed axial advancement. As another example, the user may select one instruction set of the device specific instruction sets **190** for the device that the user is controlling via bedside system **12** and may select another instruction set for the type of movement (e.g., pulsed movement, corkscrew movement, etc.). In another embodiment, the user may also select an additional instruction set associated with the type of procedure being performed (e.g., diagnostic, therapeutic, etc.). In other embodiments, a subset of the available movement instruction sets of movement instruction module **114** may be selectable by the user (e.g., profiles **182** and **184**), and another subset of the available movement instruction sets of movement instruction module **114** may be automatically selected by controller **40**, as described in more detail below. Once one or more instruction sets of movement instruction module **114** are activated, bedside system **12** will be operated based upon the user's manipulation of controls **16** and based upon the one or more activated instruction set.

In some embodiments, procedure control module **98** may be configured to automatically select or activate one or more of the available instruction sets of movement instruction module **114** based upon data available to or received by controller **40**. In one embodiment, the instruction set that is automatically activated is associated with a feature of the percutaneous device being controlled. In various embodiments, the feature of the percutaneous device may include the type, make, model and a physical property of the percutaneous device. In one such embodiment, the user may indicate the type of percutaneous device being used for a procedure, and procedure control module **98** may automatically activate the instruction set associated with that particular type of percutaneous device. The user may indicate the type of percutaneous device by any suitable means, for example, entry of the name, model number, or other iden-

tifying information of the percutaneous device via a keyboard, selection of the particular percutaneous device from a list, scanning of a barcode associated with the percutaneous device with a barcode reader in communication with controller 40, etc. In another embodiment, catheter procedure system 10 may include an RFID reader that reads an RFID tag containing identifying information associated with a percutaneous device that has been loaded into bedside system 12. The identifying information or data read by the RFID reader may then be communicated to procedure control module 98, and procedure control module 98 may select the appropriate instruction set from movement instruction module 114 based on the identifying information read by the RFID reader.

In one embodiment, assist module 102 may be configured to provide information to the user (e.g., via display on monitor 26 and/or 28, etc.) to aid in the selection of the proper instruction set of movement instruction module 114 for a particular procedure. In one embodiment, assist module 102 may display a suggestion to the user regarding which instruction set should be activated for a particular procedure. In one embodiment, the suggestion generated by assist module 102 may be based on analysis of image data of a patient acquired during a diagnostic or therapeutic procedure. In one embodiment, assist module 102 may be configured to assess one or more property (e.g., density, degree of calcification, etc.) of a lesion (e.g., an atherosclerosis, etc.), and may suggest a movement instruction set suitable for traversing the lesion with the percutaneous device. For example, if a particular lesion is identified to have a high degree of calcification, assist module 102 may select a movement instruction set suitable to allow the percutaneous device to traverse the lesion, such as a pulsed movement instruction set with a relatively low pulse duration may.

As mentioned, catheter procedure system 10 may be used to perform catheter based medical procedures. Typically, catheter based medical procedures involve the placement of a guide wire at a desired location in a patient's arterial system (e.g., the distal end of the guide wire positioned at or past a target lesion). Controller 40 may be used to operate bedside system 12 to advance a guide wire through a patient's arterial system until the distal end of the guide wire is positioned at the desired location. FIG. 6 illustrates a method for navigating a guide wire in accordance with an embodiment. At block 302, the guide wire navigation process is begun. In an exemplary procedure, the guide wire may be inserted into an incision in the patient and, for example, into the femoral artery. At block 304, bedside system 12 is operated to advance the guide wire through the arterial system. In one embodiment, a user operates the bedside system 12 by manipulation of controls 16. For example, controller 40 generates control signals based upon the user input and controls the bedside system 12 (e.g., the guide wire advance/retract actuator 72) to advance the guide wire along a path through the coronary anatomy. The path may be traversed in discrete length steps based on the input provided by the user. In another embodiment, the user may provide a set of parameters that define a predetermined path to, for example, a target lesion. In this embodiment, controller 40 is configured to automatically advance the guide wire along the predetermined path. For example, the movement instruction module 114 of controller 40 may include a guide wire navigation module 192 (shown in FIG. 5) that is configured to control the bedside system 12 to advance the guide wire along the predetermined path.

At block 306, it is determined whether the guide wire is advancing through the proper path. FIG. 7A illustrates an

exemplary path to a lesion in the heart. In FIG. 7A, a guide wire 402 is passed through a guide catheter 404 into an artery 412 of the heart 406. A path to a target lesion 408 may, for example, pass through one or more junction points 414 in the coronary anatomy. The guide wire 402, in particular a distal end 410 of the guide wire 402, needs to be advanced through the proper vessels to reach the desired location, for example, the target lesion 408. In one embodiment, an imaging system 32 may be used to provide fluoroscopic images of a region of interest showing the path to the target lesion. The images may be displayed (for example, on a monitor 26, 28) and used to determine if the guide wire is passing through the correct passageway (or vessel) to reach the desired location. In one embodiment, a user may view the images on a display to determine the location of the guide wire. In another embodiment, controller 40 may be configured to process the images to determine the location of the guide wire.

Referring to FIG. 7A, the distal end 410 of the guide wire is within side branch 418 after junction 414 and not within the correct branch 416 of the correct path. Returning to FIG. 6, if the guide wire is not advancing along the correct path at block 306 (e.g., the guide wire does not track into the correct vessel or branch 416 at a junction point but is in side branch 418), the user may provide an input to operate the bedside system 12 to retract the guide wire. In another embodiment, the controller 40 may be configured to automatically retract the guide wire when it is determined that the guide wire is not advancing along the correct path. In this embodiment, the guide wire navigation module 192 may be configured to automatically retract the guide wire. At block 308, the controller 40 (for example, the guide wire navigation module 192) is configured to control the bedside system 12 to rotate and retract the guide wire in response to a control signal to retract the guide wire. In one embodiment, the guide wire is rotated and then retracted. In another embodiment, the guide wire may be retracted and then rotated. In yet another embodiment, the guide wire is rotated and retracted simultaneously. Accordingly, the guide wire rotates while being retracted. In one embodiment, the proximal end of the guide wire is rotated (e.g., using a guide wire rotate actuator) a predetermined amount (e.g., 180 degrees). In another embodiment, the guide wire may first be rotated a first amount in a first direction and then rotated a second amount in the opposite direction. FIG. 7B shows a guide wire 402 retracted to a point before the junction 414. In one embodiment, the guide wire 402 is retraced a distance that positions the distal end 410 of the guide wire before the junction point 414. As mentioned, the guide wire is rotated while being retracted. In another embodiment, if it is required to retract the guide wire multiple times to position the distal end 410 prior to the junction 414, the guide wire may only be rotated with the first retraction of the guide wire.

At block 310 of FIG. 6, bedside system 12 is operated to advance the guide wire. FIG. 7C shows the guide wire 402 advanced past the junction point 414 and into the desired path to the target lesion 408. In one embodiment, a user operates the bedside system 12 by manipulation of controls 16. In another embodiment, controller 40 (for example, guide wire navigation module 192) is configured to automatically advance the guide wire along a predetermined path. At block 306 of FIG. 6, if the guide wire is still not advancing along the correct path, steps 306 to 310 are repeated until the guide wire is located in the correct passageway. In one embodiment, the controller 40 (for example, guide wire navigation module 193) is configured

to automatically repeat the iterations of steps 306 to 310 until a user provides an input indicating the guide wire is in the correct passageway. In one embodiment, the amount of rotation of the guide wire is changed for each retraction of the guide wire (i.e. with each iteration). At block 312, it is determined whether the guide wire is positioned at the desired location (e.g., at a target lesion). If the guide wire is not at the proper location, the process returns to block 304 and the guide wire is advanced. If the guide wire is at the desired location, the next steps in the catheter procedure may begin at block 314. For example, a working catheter may be positioned and a therapeutic procedure performed.

Computer-executable instructions for navigating a guide wire according to the above-described method may be stored on a form of computer readable media. Computer readable media includes volatile and nonvolatile, removable, and non-removable media implemented in any method or technology for storage of information such as computer readable instructions, data structures, program modules or other data. Computer readable media includes, but is not limited to, random access memory (RAM), read-only memory (ROM), electrically erasable programmable ROM (EEPROM), flash memory or other memory technology, compact disk ROM (CD-ROM), digital versatile disks (DVD) or other optical storage, magnetic cassettes, magnetic tape, magnetic disk storage or other magnetic storage devices, or any other medium which can be used to store the desired instructions and which may be accessed by system 10 (shown in FIG. 1), including by internet or other computer network form of access.

Further modifications and alternative embodiments of various aspects of the invention will be apparent to those skilled in the art in view of this description. Accordingly, this description is to be construed as illustrative only. The construction and arrangements, shown in the various exemplary embodiments, are illustrative only. While the current application recites particular combinations of features in the claims appended hereto, various embodiments of the invention relate to any combination of any of the features described herein whether or not such combination is currently claimed, and any such combination of features may be claimed in this or future applications. Any of the features, elements, or components of any of the exemplary embodiments discussed above may be used alone or in combination with any of the features, elements, or components of any of the other embodiments discussed above. Although only a few embodiments have been described in detail in this disclosure, many modifications are possible (e.g., variations in sizes, dimensions, structures, shapes and proportions of the various elements, values of parameters, mounting arrangements, use of materials, colors, orientations, etc.) without materially departing from the novel teachings and advantages of the subject matter described herein. Some elements shown as integrally formed may be constructed of multiple parts or elements, the position of elements may be reversed or otherwise varied, and the nature or number of discrete elements or positions may be altered or varied. The order or sequence of any process, logical algorithm, or method steps may be varied or re-sequenced according to alternative embodiments. Other substitutions, modifications, changes and omissions may also be made in the design, operating conditions and arrangement of the various exemplary embodiments without departing from the scope of the present invention.

What is claimed is:

1. A method for navigating a guide wire during a catheter procedure, the method comprising:
 - advancing a guide wire through a desired path of an anatomy to a point proximate a junction;
 - changing the orientation of a distal end of the guide wire by retracting the guide wire in response to a first user input and
 - automatically rotating a proximal end of the guide wire using a catheter procedure system a predetermined amount while the guide wire is being retracted to a point before the junction in response to a second user input; and
 - advancing the distal end of the guide wire past the junction through the desired path.
2. A method according to claim 1, wherein the proximal end of the guide wire is rotated a predetermined amount independent of the desired path.
3. A method according to claim 1, wherein the guide wire is retracted a predetermined amount.
4. A method of claim 1, wherein rotating the proximal end of the guide wire includes rotating the guide wire about a longitudinal axis of the guide wire using a guide wire rotate actuator.
5. A method of claim 4, wherein the second user input includes activation of a touchscreen icon.
6. A method of claim 4, wherein the second user input includes a mouse interacting with information displayed on a monitor.
7. A method according to claim 1, wherein the steps of advancing the guide wire and rotating while retracting the guide wire are repeated until the guide wire is in the desired path.
8. A method according to claim 1, further including:
 - receiving a set of parameters defining the desired path of an anatomy passing at least one junction point at a correct first branch and a side branch.
9. A method according to claim 8, wherein rotating the guide wire includes rotating the guide wire a first amount in a first direction and then rotated rotating a second amount in the opposite direction.
10. A method according to claim 9, further including:
 - advancing the guide wire through the desired path and
 - determining if the distal tip of the guide wire is in the desired path based at least on at least one image of a region of interest past the junction point using a controller of the catheter procedure system.
11. A method according to claim 10, wherein retracting the guide wire includes rotating the guide wire while retracting the distal tip of the guide wire to a position before the junction point if the distal tip of the guide wire is not in the desired path past the junction point.
12. A method according to claim 11, further including repeating the steps of advancing the guide wire, determining if the distal tip of the guide wire is in the desired path, and retracting the guide wire until the guide wire is in the desired path, wherein the guide wire is rotated only with the first retraction of the guide wire.
13. A method according to claim 8, wherein the proximal end of the guide wire is rotated a predetermined amount independent of the desired path.
14. A method according to claim 8, wherein the guide wire is retracted a predetermined amount.

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15. A method of claim **8**, wherein rotating the proximal end of the guide wire includes rotating the guide wire about a longitudinal axis of the guide wire using a guide wire rotate actuator.

16. A method of claim **15**, wherein the first user input includes activation of a joystick. 5

17. A method of claim **16**, wherein the second user input includes activation of a touchscreen icon.

18. A method of claim **16**, wherein the second user input includes a mouse interacting with information displayed on a monitor. 10

19. A method of claim **1**, wherein the first user input includes activation of a joystick.

20. A method according to claim **1**, wherein the guide wire is rotated while retracted in response to the first user input to retract the guide wire when the second user input has been selected. 15

21. A method according to claim **1**, wherein rotating the guide wire includes rotating the guide wire a first amount in a first direction and then rotating a second amount in the opposite direction. 20

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22. A catheter procedure system comprising:
a bedside system comprising a guide wire, a guide wire advance/retract actuator coupled to the guide wire and a guide wire rotate actuator coupled to the guide wire; and

a control system coupled to the bedside system, the control system comprising:

a user interface including a first user input and a second user input;

at least one display;

a controller having a mode selection module programmed to:

automatically rotate a proximal end of the guide wire about a longitudinal axis of the guide wire a predetermined amount using the guide wire rotate actuator while the guide wire is being retracted and wherein the mode selection module is programmed to only automatically rotate the guide wire during the first retraction of the guide wire when the guide wire is retracted multiple times.

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